

REMARKS

Claims 1-5, 7-14, 16, 17, 20, 22, 23, 25 and 26 are pending in the subject application.

Rejection of Claims Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1-5, 7-14, 16, 17, 20, 22, 23, 25 and 26 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled by the specification. The Examiner acknowledges that the specification enables the claimed method only in regards to the detection of modified forms of albumin. However, the detection of other proteins and asserts that it has not been established that the presence of other proteins is indicative of kidney malfunction. The Examiner also states that other intact modified proteins would be patient specific and therefore, would not be useful for detecting intact modified proteins in other patients.

Applicant respectfully disagrees with the examiner's conclusions.

During an interview with the Examiner on March 17, 2004, Applicant and the Examiner discussed how as a general matter, the increasing presence of intact modified protein in the urine correlates with renal disease and/or renal complications of a disease. As demonstrated by the published literature enclosed herewith, the skilled practitioner does not need to know which protein or proteins are present in the urine to diagnose renal complications. Generally, albumin is detected by the diagnostitian, but that is simply because there are assays available for the detection of urinary albumin. However, the presence of any protein in the urine (not protein fragments) is an indication that the kidneys are not functioning properly.

As evidence of this phenomenon, the Comper declaration filed August 15, 2003, shows the detection of intact modified proteins such as IgG and transferrin in diabetic rat urine. (courtesy copy enclosed). As can be seen by the enclosed article published by the National Kidney Foundation, diabetes results in injury to the small blood vessels of the kidneys, which, in

turn, results in increased amount of protein in the urine. Applicant's declaration provides evidence of two such proteins that are present in the urine of diabetic animals as a result of such damage to the kidneys.

Applicant's data clearly show that the methods of the present invention provide urinary protein profiles that are significantly different from those obtained using conventional methods for measuring protein, *e.g.*, immunoassay. The methods of the present invention provide a much more accurate measurement of protein content in urine. Moreover, the data also show that detection of intact modified protein by the methods of the invention provides an early indicator of renal disease.

The Comper declaration demonstrates that the methods taught in the specification allow the skilled artisan to detect intact modified IgG and transferrin protein in the same manner as the albumin. These methods can be applied to any protein present in the urine.

The Examiner's comment concerning an alleged patient-specificity of intact modified protein is unfounded. There is no evidence of patient-specificity of protein modification and in fact, the proteins are modified on the basis of their structure. Applicant's declaration demonstrates that the claimed methods are universally applicable.

Applicant respectfully submits that the specification enables the ability to detect intact modified forms of not only albumin, but of any protein, and relate the detection of such protein in the urine to the presence of renal disease and/or renal complications of a disease.

Accordingly, the rejection of claims 35 U.S.C § 112, first paragraph is respectfully traversed.

It is respectfully submitted that the present application is in condition for allowance, an early notification thereof being earnestly solicited. To the extent necessary, a petition for an

extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,


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